Message

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Sent: 5/15/2020 5:34:06 PM
To: Mohr, Ashley [Mohr.Ashley@epa.gov]; Kaleri, Cynthia [kaleri.cynthia@epa.gov]; Wilson, Aimee [Wilson.Aimee@epa.gov]
Subject: FW: FYI - Some notes & weblinks for TCEQ final EtO DSD, Final Report for Letter Peer Review & EtO DSD External Peer Review Response to Comments

FYI on this.

From: Casso, Ruben <Casso.Ruben@epa.gov>
Sent: Friday, May 15, 2020 12:23 PM
To: Garcia, David <Garcia.David@epa.gov>; Talton, Anthony <Talton.Anthony@epa.gov>; Robinson, Jeffrey <Robinson.Jeffrey@epa.gov>; Verhalen, Frances <verhalen.frances@epa.gov>
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Subject: FYI - Some notes & weblinks for TCEQ final EtO DSD, Final Report for Letter Peer Review & EtO DSD External Peer Review Response to Comments

https://www.tceq.texas.gov/toxicology/ethylene-oxide

Background
Key Points From The TCEQ Ethylene Oxide Carcinogenic Dose-Response Assessment
Assessment Basis
Early Childhood Adjustment
Cancer Assessment
Model Fit
Endogenous Production
Healthy Worker Effect

…Responding to public comments resulted in an improved **revised draft EtO DSD** (dated January 31, 2020) that underwent an external expert peer review. The external scientific peer review was organized by the University of Cincinnati Risk Science Center and produced the **Final Report for Letter Peer Review** (dated April 30, 2020).
Scientific expert comments were thoroughly reviewed and addressed by the TCEQ as documented in the **EtO DSD External Peer Review Response to Comments** (dated May 15, 2020). The TCEQ responding to the external expert comments resulted in a state-of-the-science **final EtO DSD** (dated May 15, 2020).

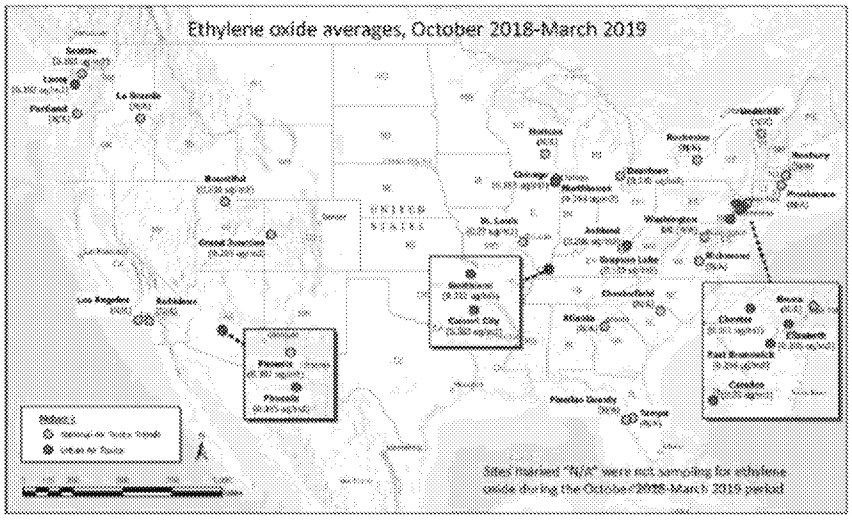
Excerpt from Executive Summary…

The most recent USEPA URF for EtO was finalized in 2016 (USEPA 2016). **Comparisons of the USEPA (2016) and TCEQ EtO URF are discussed in Appendix 6.** The EtO hazard identification and dose-response assessment described in this document consider new data and/or analyses from the scientific literature that were not

available in 2016 (e.g., Vincent et al. 2019, Marsh et al. 2019, IARC 2019, Kirman and Hays 2017) as well as new TCEQ analyses, including dose-response model predictions of the underlying NIOSH lymphoid cancer data, evaluation of the potential for healthy worker effects for EtOspecific cancer endpoints, Cox proportional hazards modeling results for multiple exposure lag durations, and validation analysis of models based on the NIOSH data using UCC data.

Thus, the TCEQ determined that use of the standard Cox proportional hazards model to derive a URF for inhalation EtO cancer risk is strongly supported by relevant considerations (e.g., TCEQ guidance, the carcinogenic MOA, standard model fit criteria combined with accurate model predictions of the key underlying cancer data, sensitivity and validation analyses). Accordingly, the TCEQ's ADAF-adjusted URF for EtO has a sound scientific basis and will be adopted for review of air concentration data and for use in air permit reviews.

National Air Toxics Trends and Urban Air Toxics monitoring sites



Urban background EtO concentrations were ≈0.1-0.2 ppb (0.185-0.397 µg/m³) with an average of 0.16 ppb (0.297 µg/m³) based on data collected for 18 sites.

If representative, urban background concentrations across the U.S. may be expected to be ≈10-20 times the maximum long-term level of 0.01 ppb that USEPA considers safe based on their demonstrably flawed EtO dose-response assessment.

By contrast, these urban background concentrations do not exceed TCEQ's long-term value of 2.4 ppb EtO based on a more recent and scientifically defensible assessment and a 1 in 100,000 excess risk level.

Excess Risk Level	TCEQ (ppb)	TCEQ (µg/m³)	USEPA (ppb)	USEPA (µg/m³)
1 in 10,000	24	43	0.01	0.02
1 in 100,000	2.4	4.3	0.001	0.002
1 in 1,000,000	0.24	0.43	0.0001	0.0002